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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 162

RIN 1625-ZA42

[Docket No. USCG-2019-0477]

Final Policy Letter Describing Type-Approval Testing Methods for Ballast Water Management Systems (BWMS) that Render Organisms Nonviable in Ballast Water

AGENCY: Coast Guard, DHS.

ACTION: Final policy; notification.

SUMMARY: The Coast Guard announces the availability of the final policy letter that describes type-approval testing methods, and the acceptance process for such methods, for ballast water management systems (BWMS) that render organisms nonviable in ballast water. At this time, the Coast Guard does not accept any type-approval testing methods for ballast water management systems that render organisms in ballast water nonviable (meaning "permanently incapable of reproduction"). In consideration of public comments on the draft policy letter, this final policy letter establishes the mechanism for reviewing and integrating viability testing methods into the existing Coast Guard type-approval testing program. The Coast Guard invites submissions of viability testing methods in accordance with the policy letter at any time following publication. The Coast Guard will review any provided information responsive to the policy letter and enclosure. This final policy letter is subject to revision, in coordination with the Environmental Protection Agency, contingent on any Coast Guard determination that a viability testing method is acceptable.

DATES: The final policy letter announced in this notification is issued as of February 28, 2022.

ADDRESSES: To view the final policy letter, as well as comments mentioned in this

notice as being available in the docket, go to *https://www.regulations.gov*, type "USCG-2019-0477," and click "Search." To see the final policy letter, click on this notice in the search results, and then click "View More Documents." To see comments, click on the July 2019 Draft Policy Letter notice in the search results, and then click "View Related Comments."

FOR FURTHER INFORMATION CONTACT: Mr. Matthew Reudelhuber, Environmental Standards Division, 202-372-1432.

SUPPLEMENTARY INFORMATION:

Table of Contents for Preamble

I. Abbreviations.

BWMS	Ballast Water Management System
CFR	Code of Federal Regulations
DHS	Department of Homeland Security
ETV	Environmental Technology Verification Program
FR	*Federal Register*
IL	Independent Laboratory
IMO	International Maritime Organization
MPN	Most Probable Number
NEPA	National Environmental Policy Act
U.S.C.	United States Code
USCG	U. S. Coast Guard
VIDA	Vessel Incidental Discharge Act of 2018

II. Background.

The Vessel Incidental Discharge Act of 2018 (VIDA) found at Title IX of the Frank LoBiondo Coast Guard Authorization Act of 2018, Pub. L. 115-282, amended Section 312(p) of the Federal Water Pollution Control Act (33 U.S.C. 1322). Pursuant to

33 U.S.C. 1322(p)(6)(D)(ii), the Coast Guard published a draft policy letter in the Federal Register on July 31, 2019 (84 FR 37330), receiving 38 submissions to the docket.

The final policy letter is issued pursuant to 33 U.S.C. 1322(p)(6)(D)(iv))which requires the Coast Guard[1] to describe type-approval testing methods, if any, for ballast water management systems (BWMS) that render organisms nonviable in ballast water and may be used in addition to the methods established in title 46 Code of Federal Regulations (CFR) subpart 162.060. As more fully discussed below, we do not describe any type-approval testing methods for BWMS that render organisms nonviable in ballast water in this policy letter. Rather, this policy letter establishes the categories of information the Coast Guard deems necessary for the evaluation of viability testing methods on the basis of best available science and describes implementation of any accepted methods. The Coast Guard will take into consideration any method that uses organism grow-out and most probable number statistical analysis to determine the concentration of organisms in ballast water that are capable of reproduction. The Coast Guard will not take into consideration any method that relies on a staining method to measure the concentration of organisms greater than or equal to 10 micrometers and organisms less than or equal to 50 micrometers. The term "stain" is undefined in VIDA and is not consistently used in science to describe a specific scientific procedure. A "stain" is defined by Merriam Webster's dictionary[2] in relevant part as a dye or mixture of dyes used in microscopy to make visible minute and transparent structures, to differentiate tissue elements or to produce specific chemical reactions. According to this definition, a "stain" acts by suffusing with color; coloring by processes affecting

[1] In DHS delegation 0170.1, the Commandant of the Coast Guard is delegated the authority to carry out the functions in section 312 of the Federal Water Pollution Control Act (33 U.S.C. 1321, et seq.) as amended by the Oil Pollution Act of 1990 (August 18, 1990; Pub L. 101-380; 104 Stat. 484).

[2] Available at https://www.merriam-webster.com/dictionary/stain?src=search-dict-hed (last accessed 01/31/2022).

chemically or otherwise the material itself. The Coast Guard will assess any evaluated type-approval testing method to determine if it utilizes a stain.

In accordance with 33 U.S.C. 1322(p)(6)(D)(iv), and 46 CFR subpart 162.060, accepted viability testing methods outlined in this policy letter or in future revisions are an alternative to testing procedures in 46 CFR subpart 162.060, including the EPA/600/R-10/146, Environmental Technology Verification (ETV) Program Generic Protocol for the Verification of Ballast Water Treatment Technologies (ETV Protocol).[3]

III. Summary of Changes from the Draft Policy Letter to the Final Policy Letter.

A. Summary of Changes.

The final policy letter contains a number of changes from the draft policy letter. This section lists all of the changes made to the draft policy letter. Most of the changes discussed below are being made as a direct response to submitted comments. A full discussion of the comments and Coast Guard responses is available at Section IV below.

1. Administrative Process

As discussed in greater detail below, several comments focused on the Coast Guard's administrative process in issuing the draft policy letter. In Section 8 of the final policy letter, titled "Process for acceptance and use of new protocols," the Coast Guard added additional details regarding the specific steps the Coast Guard will undertake in fulfilling the administrative procedural requirements associated with accepting a type-approval testing method.

2. Coast Guard Awareness of Available Testing Methods.

As discussed in greater detail below, many comments were directed at the Coast Guard's statement in the draft policy letter that, "[a]t the time of [publication of the draft policy letter], the Coast Guard does not know of any type-approval testing protocols for

[3] Available at Generic Protocol for the Verification of Ballast Water Treatment Technology | Science Inventory | US EPA (last accessed 03/31/2021)

BWMS that render organisms nonviable in ballast water that are based on best available science." In light of those comments, in the final policy letter the Coast Guard clarifies that it is not that we are unaware of viability testing methods; rather we are unaware of viability testing methods that are *based on best available science*. As more fully explained below, the acceptability of viability testing methods is predicated on these methods being based on best available science, which requires the ability to access and evaluate the supporting scientific information.

3. Acceptance of Facility or Site-Specific versus Generally Applied Testing Methods.

In the draft policy letter, the Coast Guard did not address the potential to accept facility or site-specific viability testing methods. This topic has been added to the final policy letter, along with an explanation below of the circumstances in which information on facility or site-specific viability testing methods would be assessed.

4. Scope and Applicability of "Permanently."

In the draft policy letter, the Coast Guard described the applicability of an accepted viability testing method within the existing type-approval testing protocol. In this final policy letter, the Coast Guard describes in detail a limitation on the applicability of the term "permanently" to those viability testing methods addressed by the final policy letter, not to any testing methods in the existing requirements in 46 CFR subpart 162.060.

5. Opportunity to Submit Viability Testing Methods.

The Coast Guard's draft policy letter explained the process for our evaluation of any data and information that we may receive for assessing a type-approval method. However, the draft policy letter focused on establishing the type of information and material that the public and stakeholders should provide to the Coast Guard in the form of proposals for specific viability testing methods. We have revised the final policy letter to clarify that the Coast Guard assumes the burden for assessing information regarding

available viability testing methods. In this policy letter, the Coast Guard provides an explanation of the best available science decision-making process. Further details can be found below in the relevant responses to comments, as well as in the final policy letter, and the Enclosure to the final policy letter.

6. Requirement to Consider Most Probable Number (MPN).

The legislative requirement in 33 U.S.C. 1322(p)(6)(D)(v) to consider MPN was not explicitly addressed in the draft policy letter. In the final policy letter, we make clear that the Coast Guard will take MPN-based methods into consideration.

7. Requirement for Minimum Precision and Accuracy.

The Coast Guard's initial position in the draft policy letter stated that viability testing methods would need to include statistical data demonstrating a stated minimum for precision and accuracy data. In response to comments, Coast Guard deleted references to such standards in the final policy letter and clarified the requirement to state that information on method risk and uncertainty, including precision and accuracy, is important to consider as part of the best available science assessment, but that there are no criteria for specific values to be met.

8. Requirement for Specific Number and Locations of Field Tests.

The Coast Guard's initial position in the draft policy letter was that viability testing methods would need to include validation data from a specific number of tests from specific locations. In response to comments, we have deleted references to minimum testing requirements in the final policy letter and clarified the basis for requesting information regarding the degree to which methods have been validated over a range of geographic locations and conditions.

9. Definition of best available science.

The definition of best available science was not addressed in the draft policy letter. In response to public comments, the Coast Guard added new text to the final policy letter to define the term.

10. Best Available Science Evaluation in Assessing Viability Testing Methods.

In the draft policy letter, the Coast Guard did not address the best available science evaluation of available information in assessing viability testing methods. In the final policy letter, the Coast Guard describes the general approach to evaluating information.

12. Equivalency to Existing Organism Enumeration Methods in ETV Protocol as a Requirement for Viability Testing Method.

In response to comments, the Coast Guard significantly modified what was written in the draft policy letter regarding equivalency with several testing method parameters in the ETV Protocol. In the draft policy letter, the Coast Guard stated that the existing regulation including the ETV Protocol "set the standard for rigor, documentation and transparency required of any BWMS type-approval testing protocol submitted to the Coast Guard for acceptance. BWMS type-approval testing for systems that render organisms nonviable will incorporate protocols based on viability and will be subject to the same level of rigor currently used for type-approval." The Coast Guard changed the final policy letter to focus on evaluating best available science, not adherence to a standard established by the ETV Protocol. The requirement for equivalency was removed from the final policy letter and the basis for the requested information is further explained in the relevant sections below.

13. Existing Testing Method as Applied to Viability Testing

In the draft policy, the Coast Guard did not describe the use of the existing testing method to test organism viability. However, in response to comments expressing confusion on this issue, in the final policy letter the Coast Guard elaborates on the VIDA

provision prohibiting the use of stains to test viability and how that relates to accepting a viability testing method for use within the existing type-approval program.

IV. Response to Comments.

A. Overview of Responses

We appreciate the public's comments to the draft policy letter. The draft policy letter remains available on the Coast Guard web site at: https://www.dco.uscg.mil/OES/Viability-Policy-Letter/. Documents related to the draft policy letter mentioned in this notice and all public comments to the draft policy letter are available in our online docket at *https://www.regulations.gov*, under Docket USCG-2019-0477, and can be viewed by following that website's instructions. For more information about privacy and submissions in response to this document, see DHS's Correspondence System of Records notice (84 FR 48645, September 26, 2018).

The Coast Guard received 39 submissions to the docket, one in duplicate. In the following section, we respond to 38 separate submissions. Each of the 38 submissions contains multiple comments on the draft policy letter. In the discussion below, we distinguish between submissions to the docket and the individual comments contained in those submissions. The comments raised the following issues, addressed below.

B. IMO Alignment.

1. General alignment.

The Coast Guard received four comments relating to general alignment between U.S. and International Maritime Organization (IMO) test requirements. One comment asserted that nonconformity between U.S. and IMO test requirements increases both ballast water management system (BWMS) operational complexity and opportunities for noncompliance. One commenter stated that the Coast Guard should accept testing protocols that align with IMO accepted testing protocols because doing so will avoid confusion that could result in wrongful discharges; increase the efficiency of ships by

removing a need to operate with increased power; and decrease discharges of Greenhouse gases due to less power being used on ships. Another comment requested that the Coast Guard align testing protocols and type-approval certificate limitations with international standards. One comment stated that the Coast Guard is blocking the intent of VIDA, which the commenter asserts is to adopt international BWMS MPN testing data, as a basis for Coast Guard BWMS type-approval.

The Coast Guard notes that nothing in VIDA nor its legislative history indicates Congressional intent to align domestic BWMS regulations with the IMO Ballast Water Management Convention. When adopting testing protocols, the Coast Guard is required to follow the evaluation criteria and factors for consideration that are articulated in VIDA. Under VIDA, the Coast Guard does not have the authority to accept viability testing methods on any basis other than an evaluation of best available science. Adopting a particular viability testing method on the basis that it would provide greater alignment with IMO or other international standards is not authorized under VIDA. Our interpretation on this issue is more fully addressed in the section immediately below.

2. Coast Guard alignment with IMO approach to MPN.

The Coast Guard received eight comments relating to Coast Guard alignment with the IMO's approach to the use of MPN statistical analysis-based methods. Two comments questioned why the Coast Guard does not follow IMO by recognizing both the vital stain method and the MPN method for 10-50 um size range. Two comments suggested that the Coast Guard has tacitly accepted the use of MPN by not objecting to or abstaining from the IMO approval process. Three comments stated that the Coast Guard should align domestic BWMS type-approval with IMO type-approval under the Ballast Water Management Convention. One comment noted the objectives of the IMO BWM Convention.

The U.S.is not a signatory to the 2004 IMO Ballast Water Management Convention, and thus the U.S. Coast Guard is not bound by acts taken pursuant to that convention. The Coast Guard cannot elect to adopt a viability testing method simply because it is on the list of methods recognized under the IMO Convention. According to 33 U.S.C. 1322(p)(6)(D)(ii), the Coast Guard must base its decision on the best available science. Widely adopted methods, including those employed by IMO Member States, can only be adopted by the Coast Guard if they can be determined to be based on the best available science for measuring viable organisms. However, the Coast Guard does not yet have the data and information necessary for making that determination, and therefore has not conducted the relevant evaluation. The Coast Guard will conduct an evaluation of available information, including the information identified and sought in the Enclosure, and make a determination, on the basis of best available science, whether to accept one or more specific methods. The Coast Guard's evaluation of information will be guided by the definition of best available science contained in the final policy letter.

C. Administrative Process.

Six comments asserted that the Coast Guard did not follow proper administrative processes by failing to conduct an impact study and by violating the Administrative Procedure Act's (APA) requirement to provide a reasoned basis for its policy letter.

Two commenters stated that the Coast Guard violated the APA by not providing a reasoned basis for its best available science determination. One comment noted that the Coast Guard has not done any impact studies for the VIDA draft policy letter. Two comments stated that the Coast Guard disregarded statutory requirements by not accepting MPN to type-approve UV BWMS. One comment requested that the Coast Guard take environmental impacts and opportunity for noncompliance into account when accepting a testing protocol.

In developing the draft policy letter, the Coast Guard attempted to provide concise guidance, responsive to the statutory directive in VIDA. This guidance sought to anticipate questions and areas of concern. However, some public comments provided the Coast Guard with specific concerns requiring more attention and clarification. The Coast Guard made changes in the final policy letter in consideration and as a direct result of public commentary on the draft policy letter. Our responses to comments provide the underlying reasoning for making specific policy decisions. In specific response, please note the discussion below in section D.1 providing the reasoned basis for the Coast Guard's determination that, at the time of publication, evaluation of best available science was impossible.

The Coast Guard did not engage in a rulemaking, due to a specific mandate from Congress to issue a policy letter, not a rule. The APA requirements for notice and comment do not apply to general statements of policy pursuant to 5 U.S.C. 553(b)(A). Moreover, neither the draft policy letter nor this final policy letter imposes legally binding obligations or prohibitions on regulated parties. This is consistent with statements of policy.

Taking into account that 33. U.S.C. 1322(p)(6)(D) requires the publication of a policy letter, the Coast Guard determined that the action falls under a categorical exclusion (CATEX) pursuant to Department of Homeland Security Management Directive 023-01, Rev. 1, associated implementing instructions, and U.S. Coast Guard Environmental Planning Policy COMDTINST 5090.1, which guide the Coast Guard in complying with NEPA (42 U.S.C. 4321 et seq.). CATEX A3 applies to the promulgation of rules, issuances of rulings or interpretations, and the development and publication of policies, orders, directives, notices, procedures, manuals, advisory circulars, and other guidance documents that are strictly administrative or procedural in nature or that implement, without substantive change, statutory or regulatory requirements. The action

of publishing this policy letter is categorically excluded under NEPA because it involves the publication of a policy that is strictly administrative or procedural and because it implements, without substantive change, statutory or regulatory requirements.[4] Furthermore, there are no extraordinary circumstances present that prevent the application of the CATEX.

Two categories of actions that are not discussed in this letter are: 1) acceptance of viability testing method(s), and 2) type-approval for proposed BWMS. The Coast Guard will issue subsequent policy letters for the acceptance of viability testing methods pursuant to 33 U.S.C. 1322(p)(6)(D)(iv)(III). The Coast Guard has provided additional information about the basis for its best available science decisionmaking in Section H. The Coast Guard further notes that these administrative actions will require comprehensive environmental review under NEPA, the preparation of a NEPA document such as an Environmental Assessment or an Environmental Impact Statement, and compliance with other environmental laws. For the purposes of NEPA, the USCG may choose to use a programmatic approach, resulting in one initial NEPA document that could assess potential environmental impacts of multiple testing methods and type-approvals. A programmatic NEPA document could alleviate the need for NEPA analyses on individual testing methods and type-approvals, or at a minimum, would narrow the scope of such NEPA reviews. Environmental reviews of actions following development of a programmatic NEPA document would be undertaken to comply with NEPA (42 U.S.C. 4321 et seq.), Department of Homeland Security Management Directive 023-01, Rev. 1, associated implementing instructions, and U.S. Coast Guard Environmental Planning Policy COMDTINST 5090.1, and all other applicable environmental mandates.

D. Assessment and Acceptance of Viability Testing Methods.

[4] Environmental Planning Implementing Procedures for CI 5090.1 Environmental Planning Policy, available at https://media.defense.gov/2020/Aug/18/2002479620/-1/-1/0/EP%20IP%20FINAL_COMBINED.PDF/EP%20IP%20FINAL_COMBINED.PDF (last accessed 10/07/2021)

1. Coast Guard awareness of available testing methods.

From the 38 submissions to the docket, the Coast Guard received 45 comments concerning its statement that it was unaware of available testing methods. Twenty-two comments interpreted the draft policy letter to mean that the Coast Guard has previously evaluated viability testing methods and determined that there were no acceptable viability testing methods based on best available science. Eight comments noted the availability of specific documentation regarding viability assessment and stated that the Coast Guard is aware (or should be aware) of the information. Eight other comments expressed skepticism about the Coast Guard's evaluation of the available information regarding methods for assessing the viability of organisms in ballast water and associated determination that none are acceptable. One comment stated that the Coast Guard must have assessed and excluded MPN as a testing method and concluded that doing so effectively excludes UV-based BWMS treatment. Three comments asserted that the Coast Guard assessed and rejected MPN. One comment stated that the Coast Guard needs to explain "why [the Coast Guard] effectively dismissed an otherwise unchallenged body of best available science." One comment stated that the Coast Guard disregarded scientific support for MPN and specific MPN protocols that may meet Coast Guard requirements. One comment stated that a U.S. delegation was present at the IMO's Working Group on Ballast Water Management, so the Coast Guard is aware of type-approval testing methods and protocols for BWMS that render organisms in ballast water nonviable.

The forty-five comments described above all concluded, for various reasons, that the Coast Guard had already evaluated information and methods, including MPN, and determined that none were acceptable. The draft policy letter apparently gave many readers the misimpression that it is the Coast Guard's position that we have no awareness of viability testing methods, generally. We wish to clear up that misimpression by

clarifying that it is not that we are unaware of viability testing methods but that we are unaware of a viability testing method that is *based on best available science.* At the time the draft policy letter was made available for public comment, the Coast Guard did not have the data and information needed for a best available science evaluation. Accordingly, the draft policy letter set out the Coast Guard's approach for collecting and evaluating information and the supporting science during a "best available science" evaluation. Thus, in addition to answering the VIDA mandates, one purpose of the draft policy letter was to receive public comment on the proposed process for acceptance and use of new testing methods – an approach that would entail assessing information regarding viability testing methods within a best available science evaluative framework. The Coast Guard could not undertake the described best available science evaluation until we considered and responded to public comment.

In completing the final policy letter, we considered all of the public comments on the best available science evaluation that we proposed in the draft policy letter as well as the specific information that was described in the draft policy letter's Enclosure that would be used in assessing available viability testing methods. A key purpose of the final policy letter, therefore, is to finalize the Coast Guard's best available science evaluative approach.

2. Acceptance of facility or site-specific versus generally applied testing methods.

The Coast Guard received three comments regarding the acceptance of facility-specific methods versus generally applied testing methods. One comment urged the Coast Guard to consider the pros and cons of standard methods compared to facility-specific procedures. One comment stated that the Coast Guard should adopt an approach to viability testing methods that would allow each test facility to develop its own specific MPN-based method(s). One comment asserted that specific media and culture conditions

used in grow-out during viability testing should be left to the discretion of individual test facilities.

The Coast Guard will consider a viability testing method that is intended for facility or site-specific use. In order to consider such methods, the Coast Guard requires information on a viability testing method's risks or uncertainties when used in a facility or site-specific manner, within the global context of type-approval testing. Such risks and uncertainties may possibly be mitigated through facility or site-specific validations during use and adjustment of method details based on facility or site-specific conditions.

E. VIDA Mandates.

1. Scope and applicability of "permanently."

The Coast Guard received six comments about the scope and applicability of the term "permanently." One comment touched on the technical aspect of the FDA/CMFDA + motility method in the ETV Protocol and its ability to characterize treated organisms as permanently dead. One comment requested that the Coast Guard explain whether viability assessment methods can be practicably applied to all organisms regulated by BWM regulations. One comment stated that the Coast Guard cannot conduct type-approval testing using the existing stain method because it cannot meet the new statutory definition of "permanently incapable of reproduction." One comment requested that the Coast Guard ensure that the accepted viability-based BWMS testing protocol demonstrate permanent incapability to reproduce. One comment asserted that the Coast Guard should exempt testing methods from VIDA's requirement to demonstrate that organisms have been rendered permanently incapable of reproduction because this VIDA requirement was not applied to methods in the ETV protocol. One commenter explained that a BWMS that merely renders organisms temporarily nonviable is insufficient to ensure the protection of the Great Lakes and, therefore, it is vitally important that a BWMS that is

not based on a live/dead standard, must be able to render organisms permanently nonviable.

The Coast Guard notes that "permanently" applies to organism reproduction under the 33 U.S.C. 1322(p)(6)(D)(i) definition of "live" and "living." As such, the term has not been previously considered in the context of the ballast water discharge standard regulations contained in 46 CFR subpart 162.060. Additionally, the statute defines the term "render nonviable" in 33 U.S.C. 1322(p)(1)(U) to mean "the action of a ballast water management system that renders the organism permanently incapable of reproduction following treatment." The Coast Guard recognizes that the new definitions in VIDA could be interpreted to impact the existing type-approval program, but, this is not the case based on the plain meaning of 33 U.S.C. 1322(p)(6)(D)(ii)(II) which states that an approved type-approval testing method that renders organisms nonviable may be used *in addition* to the methods established under 46 CFR subpart 162.060. The Coast Guard will evaluate the scope of any methods considered for acceptance to determine whether the method would be acceptable for enumeration of all organisms in ballast water, or only a specific subset. The Coast Guard will also assess the degree to which any viability testing methods enumerate organisms that have been permanently incapable of reproduction, i.e. are not capable of repair and recovery of reproductive ability. Finally, the Coast Guard is not authorized to "exempt" methods from the statutory requirement to enumerate organisms that have been rendered permanently incapable of reproduction.

2. Definition of "viable."

The Coast Guard received one comment suggesting a definition for the term "viable" to mean an organism that is "capable of growth and replication and hence survival." The Coast Guard notes that VIDA does not define the individual terms "viable" or "nonviable." However, VIDA does define the term "render nonviable" (in 33

U.S.C. 1322(p)(1)(U)) thus: "The term 'render nonviable', with respect to an organism in ballast water, means the action of a ballast water management system that renders the organism permanently incapable of reproduction following treatment." Accordingly, the Coast Guard determines that the definition of "viable" is capable of reproduction.

3. Coast Guard latitude in considering viability testing methods.

The Coast Guard received four comments speaking to the agency's latitude in considering viability testing methods. One comment stated a preference for the VIDA standard to be based on live/dead status of organisms, not viability. One comment requested that the Coast Guard evaluate risks posed by the introduction of living but nonviable organisms. One comment asserted that requiring BWMS to kill organisms rather than render them nonviable provides no additional disinfection benefit. One comment requested that the Coast Guard recognize a viability assessment in approving BWMS.

These comments seem to assert that either the Coast Guard should consider a viability standard or not consider it; or at least not consider it until the Coast Guard first evaluates the risks posed by introduction of living but nonviable organisms. The Coast Guard has no discretion in this area. The legislation in 33 U.S.C. 1322(p)(6)(D) requires that we consider viability testing protocols.

4. Opportunity to submit viability testing methods.

The Coast Guard received two comments regarding the request for the public and stakeholders to submit viability testing methods. One comment stated that, contrary to Congressional intent, the Coast Guard shifted the burden of validating BWMS testing protocols onto manufacturers instead of the agency. One comment interpreted the draft policy letter's proposed procedure to mean that BWMS manufacturers would submit methods as part of type-approval testing.

These comments suggest that the Coast Guard is not fulfilling its Congressional

mandate to assess viability testing methods. This is not the case. The statute requires a viability testing method to be *based on best available science*. In order to meet this requirement, we have determined that the most efficient and cost effective method of collecting relevant information on best available science is to first describe that information in detail in the Enclosure to the policy letter. The final policy letter sets forth the mechanism for stakeholders to submit viability testing methods and associated supporting information such as documentation of validation studies, the scientific basis for the method, and assumptions or requirements, as described in the Enclosure to the policy letter. The Coast Guard cannot accept a viability testing method without assessing several critical aspects of information, namely method scope, details, and validation. In evaluating best available science, the Coast Guard may assess publically available information in addition to that submitted, to ensure all aspects of the best available science definition above are fully and accurately described. At the time that a viability testing method is accepted, the Coast Guard will revise the final policy letter in accordance with 33 U.S.C. 1322(p)(6)(D)(iv)(III) .

5. Applicability of the qualifier "if any."

The Coast Guard received one comment asserting that the term "if any" in 33 U.S.C. 1322 (p)(6)(D)(ii) refers to BWMS, not type-approval testing methods and protocols.

The Coast Guard notes that the statute's location of the qualifier "if any" differs between the draft policy letter and the final policy letter. However, based on the plain reading of the statute pertaining to the final policy letter (33 U.S.C. 1322(p)(6)(D)(iv)(I), we believe the "if any" language applies to type-approval testing methods. Therefore, the Coast Guard determines that the statute's different location of the qualifying "if any" language does not affect the need to evaluate the science supporting a viability testing method within a best available science evaluative framework.

6. Requirements to issue policy "in coordination with" the EPA.

The Coast Guard received one comment questioning whether the Coast Guard had coordinated with EPA in concluding that no methods were available. We appreciate the question and would again like to emphasize that we did not mean to suggest or imply in the draft policy letter that there are no available viability testing methods, but rather that we have not evaluated the science supporting any viability testing methods within a best available science evaluative framework. We discuss this point in Section D.1.under the paragraph header "Coast Guard awareness of available testing methods." Second, the Coast Guard received EPA's input on the draft policy letter and integrated that input into the draft policy letter prior to its publication in the Federal Register.

7. Determination of no acceptable viability testing methods.

The Coast Guard received eight comments on the determination of no acceptable viability testing methods. One comment disagreed with the Coast Guard's determination not to accept any testing method that uses grow-out for organisms greater than or equal to 10 micrometers and less than or equal to 50 micrometers because the existing type-approval testing method for bacteria relies on organism grow-out. Six comments requested that the final policy letter identify one or more accepted methods, and further assert that the Coast Guard does not have discretion to determine that none are acceptable. One comment asserted that Congress's clear intent was for the final policy letter to be a final action incorporating the best MPN or similar method(s), not the starting point for a new method evaluation using a pre-existing regulatory process.

The Coast Guard disagrees with the equivalency between the existing testing method for bacteria and acceptance of a testing method that uses grow-out for organisms greater than or equal to 10 micrometers and less than or equal to 50 micrometers. The Coast Guard notes that utilizing selective media to enumerate specific organisms is fundamentally different from enumerating mixed assemblages of organisms. Further, at

the time of the ETV Protocol development, those specific methods for bacteria existed as fully validated standard methods.

In response to comments asserting that the Coast Guard was required to describe in the draft policy letter, one or more viability testing methods, Congress provided the Coast Guard with the discretion to determine "if any" type-approval testing methods are acceptable. The Coast Guard disagrees with the assertion that we were required to accept a testing method from those currently available. The statute does not require us to accept currently available viability testing methods but to accept viability testing methods that are based on best available science. As explained above, the Coast Guard's acceptance of viability testing methods must result from assessing information regarding viability testing methods within a best available science evaluative framework.

The Coast Guard disagrees that the final policy letter is required to be a final action with no ongoing assessment of viability testing methods. Nor do we agree that we have made the policy letter "the starting point for a new method evaluation using a pre-existing regulatory process." Under 33 U.S.C. 1322(p)(6)(D)(iv)(III), Congress expressly contemplates an ongoing assessment of viability testing methods by directing the Coast Guard to incorporate accepted viability testing methods into future revisions of the final policy letter. We have determined that a revision of the policy letter will require several steps prior to completing the action of accepting a viability testing method. We must collect relevant information about viability testing methods, assess that information, and comply with any implicated legal authorities such as NEPA. Consequently, any prospective acceptance of a viability testing method will require comprehensive environmental review under NEPA, the preparation of a NEPA document such as an Environmental Assessment or an Environmental Impact Statement, and compliance with other environmental laws. VIDA did not waive, and we cannot choose to ignore, these requirements. The Coast Guard must adhere to these procedural requirements and,

together with the assessment of the information necessary to accept a type-approval testing method, it was not possible to accept a type-approval testing method within the 180 day timeframe that the statute provided with respect to the final policy letter.

The Coast Guard published a draft policy letter that sought public comment on the process for acceptance and use of new protocols. This process, incorporated in the final policy letter, will help the Coast Guard assess viability testing methods based on best available science. At the time that the Coast Guard accepts a viability testing method using the criteria established in the policy letter, we will revise the policy letter to reflect the Coast Guard's acceptance in accordance with 33 U.S.C. 1322(p)(6)(D)(iv)(III).

8. Applicability of "Best Available Science" Requirement.

The Coast Guard received three comments asserting that the Coast Guard did not base its draft policy letter on best available science.

Of these three comments that generally assert that the draft policy letter was not based on the best available science, one commenter specifically asserted that the Coast Guard misinterpreted the statutory directive because the Coast Guard "issue[d] a draft policy letter that is not based on best available science [nor did it] discuss what best available science is or what it shows." The commenter goes on to say that, "instead USCG appears to have interpreted the statutory directive to ask USCG to determine whether there are any type-approval methods that are themselves based on best available science."

With respect to the draft policy letter, 33 U.S.C. 1322(p)(6)(D)(ii), requires the Coast Guard to, "publish a draft policy letter, *based on the best available science*, describing type-approval testing methods and protocols for BWMS, if any…" (Emphasis added). With respect to the final policy, 33 U.S.C. 1322(p)(6)(D)(iv) requires the Coast Guard to, "publish a final policy letter describing type-approval testing methods, if any, for ballast water management systems that render nonviable organisms in ballast water …

[that] shall be evaluated by measuring the concentration of organisms in ballast water that are capable of reproduction *based on the best available science* that may be used in addition to the methods established under subpart 162.060 of title 46, Code of Federal Regulations (or successor regulations)." (Emphasis added). Though the wording in 33 U.S.C. 1322(p)(6)(D)(ii) and (iv) differs slightly, we interpret their meaning to be the same - the Coast Guard's acceptance of viability testing methods must result from assessing information regarding viability testing methods within a best available science evaluative framework. Consequently, one purpose of the draft policy letter was to receive public comment on the proposed process for acceptance and use of new testing methods – an approach that would entail assessing information regarding viability testing methods within a best available science evaluative framework.

9. Requirements to consider MPN.

The Coast Guard received eight comments regarding the requirement to consider MPN. Four comments asserted that VIDA requires the Coast Guard to adopt the MPN method. Two comments asserted that VIDA requires the Coast Guard to consider MPN in the draft policy letter. One comment stated that Coast Guard must accept a culture-based viability testing protocol because that is the only way to determine if an organism is permanently incapable of reproduction. One comment stated that the "MPN method" is intended to be added to the Coast Guard BWMS type-approval testing requirements.

VIDA requires that, in developing the final policy letter, the Coast Guard "take into consideration a testing method that uses organism grow-out and most probable number statistical analysis." The Coast Guard's final policy letter reflects the requirement to consider such testing methods. We note that the requirement to consider organism grow-out and most probable number statistical analysis were not included in the VIDA mandate for the draft policy letter; consequently, we did not address it.

The Coast Guard does not consider the term "MPN" to refer to any specific method intended to determine the concentration of viable organisms in ballast water. MPN is a general procedure that uses serial dilutions and statistical calculations to estimate concentrations of organisms in original samples and the organism grow-out is used to identify viable organisms. There can be many different specific methods that incorporate MPN or grow-out to identify numbers of viable organisms. Different methods may target specific organisms or broad assemblages of organisms depending on the selection of growth media and conditions. The Coast Guard is required to assess the permanency of an organism's inability to reproduce and will do so under a best available science evaluative framework.

F. Equivalency to ETV Protocol as a Requirement for Viability Testing Method.

1. Requirement for minimum precision and accuracy.

The Coast Guard received two comments directed at the requirement in the draft policy letter enclosure for the precision and accuracy of viability testing methods to be at least equivalent to the precision and accuracy of methods accepted in existing regulations. The first comment points out that because VIDA does not require an equivalent level of precision and accuracy, the Coast Guard should remove this requirement. We agree that the ETV Protocol's precision and accuracy are not benchmarks for a viability testing method. However, we must assess the precision and accuracy for two reasons. First, we must evaluate the scientific information supporting a testing method in a manner that maximizes the quality, objectivity, and integrity of information, including statistical information. Second, we must evaluate the scientific information that supports a testing method in a manner that clearly documents and communicates risks and uncertainties in the scientific basis. Therefore, we are considering those categories of information.

The other comment noted that lesser precision and accuracy of best available methods for evaluating nonviable organisms, compared to existing methods for dead organisms, should not disqualify a proposed method.

We acknowledge that the existing testing method under 46 CFR subpart 162.060 was never evaluated on the basis of best available science. However, VIDA included a best available science criteria relating to viability testing methods. As stated above, we have determined that a best available science evaluation requires the Coast Guard to collect information, including that regarding precision, accuracy and associated statistical calculations for any potential viability testing method.

2. Requirement for specific number and locations of field tests.

The Coast Guard received one comment disagreeing with requirements in the draft policy letter's enclosure regarding the validation of viability testing methods be conducted at a specific number of locations in the U.S. because organisms in the U.S. are not aquatic nuisance species.

The Coast Guard agrees that there should not be a requirement for a specific number or geographic range of validation locations. Accordingly, in the final policy letter, the Coast Guard changed the requirement such that the focus is on demonstrating the viability testing method's capability to effectively quantify organisms over the geographic range of its intended use, not on meeting a specific number of test locations.

3. Requirement for general consistency with the existing testing method.

The Coast Guard received eight comments relating to the requirement for consistency with the ETV Protocol when it comes to viability testing methods. Three comments disagreed with requirements specified in the draft policy letter's enclosure as being inconsistent with or exceeding the ETV Protocol's requirements. Another comment stated that the ETV Protocol cannot be used as the standard for scientific rigor in assessing viability testing methods. One comment requested the Coast Guard describe

the level of scientific rigor applied in accepting the existing testing method. One comment asserted that the Coast Guard's acceptance of the existing testing method created the comparative level of scientific rigor that must be considered when assessing viability testing methods. One comment stated that a significant flaw in the existing type-approval testing method is that it does not incorporate an incubation period and therefore does not test the ability of organisms to repair after a measurement of dead status. One comment stated that the use of a vital stain is not an accurate assessment of living organisms.

The Coast Guard agrees with the commenters' statements that the ETV Protocol should not establish the standard for acceptance of type-approval testing protocols. The Coast Guard acknowledges that the ETV Protocol is not "perfect science" and that the acceptance of testing methods under that protocol does not set a requirement for acceptance under VIDA. In establishing a best available science evaluative framework, we have determined that the categories and types of information described in the Enclosure to the policy letter are appropriate and necessary in assessing viability testing methods.

G. Identification of BWMS that are Type-Approved on the Basis of Viability.

The Coast Guard received three comments on the requirement that BWMS type-approval certificates be annotated to differentiate between BWMSs approved on the basis of viability and those that are approved based on rendering organisms dead.

In response to these comments, the Coast Guard refers to 33 U.S.C. 1322(p)(6)(D)(ii)(II)(bb) which includes the explanation that a testing method is used "to certify the performance of each ballast water management system [that renders organisms nonviable in ballast water]." To carry out this requirement, the Coast Guard determined that BWMS tested to a viability standard must be certified as such. Consequently, the final policy letter retains the requirement to annotate a BWMS type-approval certificate

to reflect the basis for approval. The Coast Guard notes that in addition to Congressional direction regarding certification of viability-based BWMS, annotation is necessary to help avoid confusion regarding the intended effect of a specific BWMS model. Under 46 CFR 162.060-10(g), the approval certificate will list conditions of approval applicable to the BWMS. We believe that an annotation to the type-approval certificate is the easiest method of avoiding confusion.

H. Best Available Science.

1. Definition of best available science.

The Coast Guard received twenty-one comments about the definition of best available science. Ten of these comments assert that the Coast Guard should adopt an MPN method as representing the best available science because it is accepted for use under the IMO Ballast Water Management Convention. Three comments assert that the Coast Guard's interpretation of best available science improperly requires "perfect science." Five comments requested that the Coast Guard provide its reason for not following guidance from the legal and scientific community on interpreting the term "best available science." Three comments asserted that submissions to the docket in response to the draft policy letter provide a best available science basis for accepting the MPN method. In response to these comments, we point out that VIDA does not define "best available science." Therefore, the Coast Guard must use its discretion in determining what constitutes "best available science." The Coast Guard notes a cogent definition for the term is found in the immediately preceding section of the Federal Water Pollution Control Act (FWPCA), 33 U.S.C. 1321(a)(27) which states: "the term 'best available science' means science that - maximizes the quality, objectivity, and integrity of information, including statistical information; uses peer-reviewed and publicly available data; and clearly documents and communicates risks and uncertainties in the scientific basis for such projects." Although not intended to apply to other sections of the FWPCA,

the Coast Guard notes that the definition in section 1321 aligns with our general understanding of other working definitions for the term “best available science” when used in federal legislation. The definition in section 1321 is concise and informative, providing three elements that can be generically applied to the evaluation of scientific information. This definition is a congressionally defined term within the same Act as the legislative requirements we are required to implement in 33 U.S.C. 1322. The Coast Guard notes that while applying this definition to the evaluation of type-approval testing methods is different from the way that the definition is applied in Section 1321, the definition speaks to the general concept of assessing scientific information, independent of the topic of that science.

2. Best available science evaluation in assessing viability testing methods.

The Coast Guard received eight comments about the best available science evaluation for assessing viability testing methods. One comment stated that the draft policy letter does not establish any specific process by which a viability-based methodology could be approved. One comment stated that it is critical that a best available science determination be based on an up-to-date understanding of the relevant science. Three comments asserted that the Coast Guard must describe a detailed process for evaluating viability testing methods, taking into consideration the best available science - including one comment seeking details on the determination of whether organisms are "permanently non-viable." Two comments asserted that the Coast Guard should research best available science before developing a process. One comment requested that the Coast Guard work with various stakeholders in developing and accepting viability-based BWMS type-approval protocols.

The Coast Guard will assess the most current data and information available that supports viability testing methods on the basis of best available science pursuant to the approach outlined in the final policy letter. The Coast Guard has not yet conducted an

assessment of supporting information and data for viability testing methods for the reasons discussed in Section D. 1. Once we complete this assessment and make a determination on acceptability, we will describe the basis for our acceptance, recognizing that the best available science evaluation itself does not result in a conclusory determination of acceptability.

I. Existing Type-Approval Testing Requirements.

1. Existing type-approval program maintained in effect.

The Coast Guard received five comments about the existing type-approval program remaining in effect. One comment agreed with the Coast Guard's conclusion that accepted viability methods would be used as part of the ETV protocol process. One comment noted that the existing type-approval testing method will remain in place until Coast Guard accepts a viability-based type-approval testing method. One comment supported a type-approval testing protocol that combined live/dead and viability assays. One comment agreed with the Coast Guard decision to add viability testing methods to the existing type-approval testing methods. One comment asserted that the final viability policy letter should not address how viability testing methods would be incorporated into the type-approval testing procedures specified in regulation.

Any accepted method will be used in addition to existing type-approval testing methods per 33 U.S.C. 1322 (p)(6)(D)(iv)(II). At the time that one or more viability testing methods are accepted, viability testing methods will only be added to the discrete sections of the type-approval test requirements for which the specific viability testing method applies. Sections 5.4.6.4 and .5 of the ETV Protocol address enumeration of organisms in ballast water. Accepted viability testing methods for organisms greater than 50 um in size would be accepted for use under Section 5.4.6.4, and viability testing methods for organisms in the 10-50 um size group would be accepted for use under 5.4.6.5. An accepted viability testing method may describe alternative procedures

relating to aspects of the ETV Protocol beyond those described above. The specifications for such alternatives will then be described in a revision to the final policy letter and must directly relate to measuring the concentration of organisms in ballast water that are capable of reproduction. Under VIDA, the Coast Guard will not assess any method that enumerates living organisms (i.e., not dead). If no viability testing methods are accepted for a specific size class or type of organism for which testing is required, then existing test methods identified in the ETV Protocol remain in effect and must be used.

2. Existing testing method as applied to viability testing.

The Coast Guard received five comments about the existing testing method as applied to viability testing. One comment states that the ETV Protocol utilizes vital stain to determine organism viability. Three comments noted that vital stain does not assess viability. Another comment claimed that testing organisms with MPN gives a better viability result than vital stains.

The existing testing method specified in the ETV Protocol does not assess organism viability, meaning the ability to reproduce, and will not be used for that purpose. Additionally, 33 U.S.C. 1322(p)(6)(D)(v)(II) prohibits the Coast Guard from considering a testing method that relies on a staining method to measure the concentration of organisms greater than or equal to 10 micrometers and less than or equal to 50 micrometers. The term "stain" is undefined in VIDA and is not consistently used in science to describe a specific scientific procedure. A "stain" is defined by Merriam Webster's dictionary[5] in relevant part as a dye or mixture of dyes used in microscopy to make visible minute and transparent structures, to differentiate tissue elements or to produce specific chemical reactions. According to this definition, a "stain" acts by suffusing with color; coloring by processes affecting chemically or otherwise the material

[5] Available at https://www.merriam-webster.com/dictionary/stain?src=search-dict-hed (last accessed 01/31/2022).

itself. The Coast Guard will assess any submitted type-approval testing method information to determine if it utilizes a stain.

J. Topics Outside the Scope of the Draft Policy Letter.

1. Information provided in support of a general or specific method.

Seventy-five comments offered support for viability testing methods. Fifty comments expressed support, either generally or for one or more specific viability testing methods. Eighteen comments cited to specific supporting information for one or more specific viability testing methods. Seven comments noted scientific information supporting MPN usage in water treatment.

The Coast Guard did not solicit information regarding potential viability testing methods in the *Federal Register* notice requesting comments on the draft policy letter. Therefore, comments proposing or supporting the acceptance of specific methods are outside the scope of the draft policy letter. Going forward, submissions in response to the final policy letter or its enclosure may include, by reference, information previously submitted to the docket in response to the draft policy letter, to avoid duplication of effort, if desired. However, the Coast Guard cautions that, when submitting information responsive to the final policy letter or its enclosure, care should be taken to ensure that any submitted viability testing method and associated scientific information and data responds to the specific categories of information identified in the final policy letter or its enclosure.

2. General support for VIDA.

The Coast Guard received five comments offering general support for VIDA. One comment agreed with VIDA's definition of "live" and "living." Two comments generally supported the use of viability-based BWMS type-approval testing. One comment stated support for the discharge of nonviable organisms in ballast water as effective in preventing the spread of invasive species. One comment supported the use of best

available science in assessing ballast water treatment options. One comment noted the importance of determining permanent nonviability.

While the Coast Guard appreciates these commenters' concern regarding ballast water treatment, we consider these six comments to be outside the scope of the draft policy letter. As discussed above, the draft policy letter sought public comment on the process for accepting type-approval testing methods and protocols for BWMS, if any, that render organisms nonviable in ballast water and may be used in addition to the existing testing methods.

3. 2012 BWDS rule requirements.

The Coast Guard received ten comments relating to the 2012 BWDS rule. One comment noted that in the 2012 BWDS rulemaking, the Coast Guard noted differences in the Coast Guard's 2012 BWDS and the IMO BWM convention. One comment claimed that existing regulations are designed to ensure ballast water sterilization. One comment claimed that Coast Guard regulations do not address the technical aspects of quantifying organisms in ballast water and that Coast Guard regulations do not touch on the methods available to treat BW to reach the thresholds (discharge standards). Six comments recommended changes to the 2012 BWDS rule, including amending BWM requirements, the BWDS, the type-approval testing protocol incorporated by reference, and adoption of emerging technologies. One comment stated that in the preamble discussion of the 2012 BWDS rule, the Coast Guard proposed to align with IMO regarding the use of viability testing methods for BWMS approvals.

While the Coast Guard appreciates these commenters' concern regarding ballast water treatment, we consider these ten comments outside the scope of the draft policy letter. As discussed above, the draft policy letter sought public comment on the process for accepting type-approval testing methods and protocols for BWMS, if any, that render

organisms in ballast water nonviable and that may be used addition to the existing testing methods.

4. BWMS protocols for the Great Lakes

The Coast Guard received one comment requesting that the Coast Guard require the use of BWMS on all ships traversing the Great Lakes, whether land based or onboard.

This comment is out of scope as it relates to use of BWMS for vessels on the Great Lakes, instead of the testing method that could be used to test BWMS. The Coast Guard acknowledges the comment and notes that VIDA addresses applicability of ballast water regulation in the Great Lakes under other provisions.

5. Agency decisions made prior to VIDA enactment.

The Coast Guard received five comments discussing Coast Guard decisions made prior to the enactment of VIDA. One comment asserted that the Coast Guard made multiple scientific errors in 2016 when the Coast Guard denied an appeal to an earlier Coast Guard decision that rejected the use of MPN. One comment stated that the Coast Guard switched rationales for not accepting MPN, asserting that the USCG rejected MPN in 2015 because it did not meet the BWDS established in the 2012 rule. Now, the commenter asserts we are rejecting MPN on the basis that MPN is not based on the best available science. One comment questioned why the Coast Guard allows culture-based methods for bacteria but not for 10-50 um organisms. Two comments objected to the Coast Guard's rejection of the MPN method for enumeration of viable microorganisms that was published in the 2015 Maritime Commons.

Prior to the enactment of VIDA, the Coast Guard made decisions under other legal authorities. Under VIDA, the Coast Guard is required to evaluate the acceptability of viability testing methods, on the basis of best available science, giving consideration to any MPN-based methods. Consequently, comments pertaining to assessment of VIDA

requirements through the lens of other authorities are not relevant to the evaluation of type-approval testing method on the basis of best available science required under VIDA.

6. Factors for consideration in assessing BWMS technology type.

The Coast Guard received fourteen comments relating to factors that Coast Guard would consider in assessing viability testing methods based on the impacts of BWMS technology type. One comment provided an opinion on the associated environmental benefits or drawbacks of particular BWM technologies. One comment requested that the Coast Guard evaluate environmental risks of technologies designed to render organisms living but nonviable. One comment mentioned that a filter and UV based BWMS requires more than three times the power consumption if designed according to results from CMFDA testing. The comment further noted that such design will not be optimal, and sometimes impossible to retrofit on-board ships in our main target market segments. The comment requested the Coast Guard consider energy usage in assessing acceptable viability-based type-approval testing methods. One comment provided an opinion on water quality impacts of UVC radiation versus other BWM treatment technologies. One comment stated that the Coast Guard's BWMS testing requirements result in UV based system having to be significantly overpowered, causing the systems to have larger footprints and consume more energy than necessary to be effective. Two comments claimed that the Coast Guard, in not accepting viability assays, is not allowing the use of UV technology. One comment stated that the Coast Guard is biased against UV-based BWMS technologies and that the Coast Guard’s rejection of low-energy UV BWMS that render certain microorganisms is contrary to the National Invasive Species Act (NISA) and international norms. One comment asserted that the Coast Guard should recognize low-dose UV as a preferred BWMS technology because it is an effective and economical treatment option for the maritime industry. One comment supported type-approval testing methods that are tailored to specific treatment technologies. One commenter

recommends grow-out methods for measuring the response of all treatments because both inactivated and killed cells will not grow out. One comment supported the use of appropriate viability testing methods for type-approving UV BWMS. One comment noted there are limitations of UV-based treatment that, in some situations, will make UV-based processes not the process of choice. One comment asserts that the Coast Guard is concerned that UV-based methods may not render organisms permanently nonviable.

Our response to these comments is that we interpret VIDA to be "technology neutral" when it comes to the acceptance of type-approval protocols. The Coast Guard determines that Congress did not express an intent to either disadvantage or create preference for any specific BWMS technologies. In other words, VIDA does not address BWMS treatment technology types beyond the general qualification that they render organisms nonviable, and the acceptance of viability testing methods is based on best available science.

V. Review of Viability Testing Methods.

The Coast Guard will revise the final policy letter once any viability testing methods are accepted. The Coast Guard invites voluntary submission of viability testing methods and associated scientific information and data responsive to the specific categories of information identified in the final policy letter or its enclosure. Upon receipt of a submission, the Coast Guard will evaluate the submitted viability testing method, and associated scientific information and data, on the basis of best available science. Afterwards, the Coast Guard will conduct NEPA-compliant environmental analysis on any potentially acceptable viability testing methods, to include any required public involvement. If, pursuant to these analyses, the Coast Guard determines that a viability testing method is acceptable, we will publish a revision of the final viability policy letter to include any accepted viability testing methods.

Revisions to the final policy letter, if any, may also occur during the 5 year review of standards of performance, pursuant to 33 U.S.C. 1322(p)(D)(iv)(III). Reviewing testing methods, immediately following any changes to standards of performance and associated type-approval requirements, will allow the Coast Guard to expedite the inclusion of changes to the type-approval regulations, including methods for testing viability, responsive to any new standards of performance.

We are mindful of the potential pitfalls associated with reviewing proposed methods submitted at any time. We note that significant resources are required to conduct the best available science evaluation of viability testing methods. Once the Coast Guard initiates review of a viability testing method, subsequent submissions will be reviewed in the order received.

In addition to participating in the revision process described above, states may petition for changes to the policy establishing the review and acceptance process, pursuant to 33 U.S.C. 1322(p)(7). Such changes would pertain to the substance of the policy letter, which establishes the process for accepting and implementing viability testing methods, and would not be for the purpose of revising the policy letter to accept a specific viability testing method. This is due to the phrasing of 33 U.S.C. 1322(p)(7), which allows for petitions to review a policy if there exists new information that could reasonably result in a change to the standard of performance, regulation, or policy or to a determination on which the policy was based.

VI. Environmental Aspect and Impact Considerations.

a. The development of the final policy letter and the general policies contained within it have been thoroughly reviewed by the Coast Guard. Pursuant to NEPA (42 U.S.C. 4321 et seq.), Department of Homeland Security Management Directive 023-01, Rev. 1, associated implementing instructions, and U.S. Coast Guard Environmental Planning Policy COMDTINST 5090.1, we have determined that publishing the final

policy letter, which does not accept a testing method, is categorically excluded under CATEX A3 listed in Appendix A, Table 1 of the Department of Homeland Security Instruction 023-01-001-01, Rev. 1.[6] We have also determined that no extraordinary circumstances exist which prevent the application of the CATEX.

CATEX A3 pertains to the promulgation of rules, issuance of rulings or interpretations, and the development and publication of policies, orders, directives, notices, procedures, manuals, advisory circulars, and other guidance documents, such as "those of a strictly administrative or procedural nature," or "those [implementing], without substantive change, statutory or regulatory requirements."

b. The final policy letter will not have any of the following: significant cumulative impacts on the human environment; substantial controversy or substantial change to existing environmental conditions; or inconsistencies with any Federal, State, or local laws or administrative determinations relating to the environment. All future specific actions resulting from the general policy in the final policy letter must be individually evaluated for compliance with NEPA (42 U.S.C. 4321 et seq.), Department of Homeland Security Management Directive 023-01, Rev. 1 and associated implementing instructions, U.S. Coast Guard Environmental Planning Policy COMDTINST 5090.1, Executive Order 12114 Environmental Effects Abroad of Major Federal Actions, and compliance with all other applicable environmental mandates.

VII. Paperwork Reduction Act.

The Coast Guard determines the final policy does not require a new collection of information under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501.

VIII. Public Availability of the Final Policy Letter.

The Coast Guard developed the final policy letter in coordination with the EPA

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[6] https://www.dhs.gov/sites/default/files/publications/DHS_Instruction%20Manual%20023-01-001-01%20Rev%2001_508%20Admin%20Rev.pdf

pursuant to 33 U.S.C. 1322(p)(6)(D)(iv). The final policy letter is available in the docket and on the following USCG web site: https://www.dco.uscg.mil/OES/Viability-Policy-Letter/. All comments received are also posted without change to *https://www.regulations.gov*. For instructions on locating the docket, see the **ADDRESSES** portion of this Federal Register document.

Dated: March 15, 2022.

Jeffrey G. Lantz,
Director of Commercial Regulations and Standards,
Office of the Commandant,
U.S. Coast Guard.
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